510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k121467

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Hematocrit

D. Type of Test:

Quantitative

E. Applicant:

Eurotrol B.V.

F. Proprietary and Established Names:

Eurotrol Hct Control and epoc® Hematocrit Verification Fluids

G. Regulatory Information:

1. Regulation section:

   21 CFR § 864.8625, Hematology quality control mixture

2. Classification:

   Class II

3. Product code:

   GLK, Control, Hematocrit

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):
   Eurotrol Hct Control is an assayed hematocrit reference material, to verify the precision and accuracy of the epoc® Blood Analysis System for the measurement of hematocrit.
   Eurotrol HCT Control is for *in vitro* diagnostic use only.

   epoc® Hematocrit Verification Fluids is an assayed hematocrit reference material, to verify the precision and accuracy of the epoc® Blood Analysis System for the measurement of hematocrit.
   epoc® Hematocrit Verification Fluids is for *in vitro* diagnostic use only.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   epoc® Blood Analysis System, manufactured by Epocal Inc.

I. Device Description:

Eurotrol Hct Control and epoc® Hematocrit Verification Fluids are assayed hematocrit reference materials, to verify the precision and accuracy of epoc® Blood Analysis System. Eurotrol Hct Control is an electrolyte solution with conductivity appropriate to simulate clinically relevant hematocrit concentrations. These quality control materials are prepared using pure chemicals in a physiologically buffered matrix and contain no preservatives or other additives that might adversely affect electrode measurements. Eurotrol Hct Control is available in 2.5 mL ampules at three different hematocrit concentration levels (A, B, C) and is packaged in 10 ampules of the same level product per carton. epoc® Hematocrit Verification Fluids are available at five distinct hematocrit concentration levels ~ 10, 20, 32, 48, and 65 %PCV. Each ampule of epoc® Hematocrit Verification Fluids contains 2.5 mL solution and 5 ampules, i.e. 1 ampule per level including instructions for use/assay sheet.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   RNA Medical QC 900 Hematocrit Control

2. Predicate 510(k) number(s):
   k955630

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Eurotrol Hct Control is an assayed hematocrit reference material, to verify the precision and accuracy of the epoc® Blood Analysis System for the measurement of hematocrit. epoc® Hematocrit Verification Fluids is an assayed hematocrit reference material, to verify the precision and accuracy of the epoc® Blood Analysis System for the measurement of hematocrit.	RNA Medical QC 900 Hematocrit Control is intended for use in monitoring the performance of the hematocrit channel on analyzers which measure the electrical conductivity of whole blood, with the conductivity corrected for sodium ion concentration and converted to hematocrit percentage through the solution of an empirical function. RNA Medical QC 900 control is for in vitro Diagnostic Use.
Analytes	Hematocrit (Conductivity)	Hematocrit (Conductivity)
Color	Clear	Clear
Control levels	5	5
Container	Clear glass ampules	Clear glass ampules

Differences		
Item	Device	Predicate
Matrix/Materials	Eurotrol Hct Control is prepared using pure chemicals in a physiologically buffered matrix. Different concentrations provide distinct Hct levels (conductivity), simulating clinically significant ranges of hematocrit.	This product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. It contains no red cells and no human or biological materials.
Filling Volume	2.5 mL	2.7 mL
Closed-vial stability	3 months	18 months
Opened-ampule stability	15 minutes	Introduce the liquid from the ampule to the system according to manufacturer's instructions.
Storage temperature	15 - 30°C	2 - 25°C

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP5-A2 Methods, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline

CLSI EP25-A Methods, Evaluation of Stability of *In vitro* Diagnostic Reagents; Approved Guideline

L. Test Principle:

Eurotrol Hct Control and epoc® Hematocrit Verification Fluids are electrolyte solutions with conductivity at three and five levels respectively, appropriate to simulate clinically relevant hematocrit concentrations useful to evaluate the measurement of the epoc® Blood Analysis System.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Data were collected internally and at two external sites across different epoc Blood Analysis systems (i.e. Epocal epoc reader and Epocal epoc cartridge). Each study site performed two runs per day in duplicate for 20 distinct days on different epoc® Blood Analysis systems using 3 lots of the 3 levels of Eurotrol Hct Control and 5 levels of epoc® Hematocrit Verification Fluids. Acceptance criterion was predetermined to be ≤9.0% CV for the total variance which was based on compilation of the CV% for Hct Control and epoc® Hematocrit Verification Fluids at the different levels. Results collected across the three manufactured lots of Hct Control and epoc® Hematocrit Verification Fluids demonstrated consistent recovery across multiple Epocal epoc® Blood Analysis System at multiple study sites and were within the specified assay assignment ranges.

Level	N	Mean (%PCV)	Within-Run		Between-Run		Between-Day		Between-Lab	
			SD (%PCV)	CV%	SD (%PCV)	CV%	SD (%PCV)	CV%	SD (%PCV)	CV%
Level 1	720	9.35	0.37815	4.04483	0.00000	0.00000	0.13737	1.46933	0.15919	1.7027
Level 2	720	19.33	0.50010	2.58755	0.11610	0.60073	0.09027	0.46704	0.21998	1.1382
Level 3	720	31.60	0.81406	2.57609	0.14595	0.46184	0.00000	0.00000	0.17771	0.5624
Level 4	720	47.43	0.95326	2.00996	0.00000	0.00000	0.00000	0.00000	0.10964	0.2312
Level 5	720	62.09	1.08734	1.75121	0.06111	0.09841	0.00000	0.00000	0.13820	0.2226

Level	Between-Lot		Total	
	SD (%PCV)	CV%	SD (%PCV)	CV%
Level 1	0.16492	1.7641	0.46304	4.95284
Level 2	0.42178	2.1823	0.70570	3.65136
Level 3	0.06787	0.2148	0.84864	2.68550
Level 4	0.88944	1.8754	1.30837	2.75871
Level 5	0.42450	0.6837	1.17700	1.89562

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Value assignment:
Value assignment is performed in two steps. The initial step is a quality control calculation of gravimetric values and measurements on different instruments at Eurotrol B.V to verify if the fluid has been manufactured within acceptable ranges. Final value assignment is performed using the BGEM cards and the epoc® Blood Analysis system to obtain values for end users. The value assignment is performed for each new fluid lot of Eurotrol Hct Control and epoc® Hematocrit Verification Fluids and on existing fluid lots after release of each new epoc System sensor configuration. Assigned values are only applicable for the particular epoc System Sensor Configuration.

Closed-vial Stability:
To demonstrate the shelf life of Eurotrol Hct Control and epoc® Hematocrit Verification Fluids, multiple ampules of batches from all levels and stored at temperatures between 15-30°C for 3 months. Hematocrit/conductivity values are measured at the following time points (0, 3, 6, 7 months). Results are analyzed using the measurand drift analysis method according to CLSI EP25-A using a 95% confidence interval (CI). The acceptance criterion is based on ±5% maximum allowed relative deviation from the mean. Real time stability studies are- ongoing at time of clearance; however sponsor has provided data that supports 3 months stability.

Open-ampule stability: The claimed stability for opened ampules is 15 minutes at room temperature.

d. *Detection limit:*

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The end-user is instructed to refer to the product assay sheet accompanying the product instruction for use. The values are applicable only to the assigned fluid lot number and the applicable epoc® Blood Analysis System sensor configuration.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.